

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,)	
)	
)	
v.)	Criminal No.
)	No. 04-10367-DPW
ADAM STUPAK,)	
)	
)	
Defendant)	

**GOVERNMENT’S RESPONSE TO THE DEFENDANT’S
SENTENCING MEMORANDUM**

The United States of America, by its attorney, Michael J. Sullivan, United States Attorney for the District of Massachusetts and Assistant U.S. Attorney Mary Elizabeth Carmody, hereby respond to those portions of the defendant’s Sentencing Memorandum with which the Government disagrees¹ and states as follows:

B. Nature and Circumstances of the Offense:

The United States disagrees with several of the points made by the defendant in Section B of his Sentencing Memorandum (at page 6-7):

1. Contrary to the assertion of the Defendant, he was in a position of authority within the Metabolic and Immune Therapy (“M&IT”) business unit of Serono Laboratories, Inc. (“Serono”) in 1999. Serono’s M&IT was a small business unit within the company. Stupak’s position as Regional Director had more responsibility than his counterparts in larger pharmaceutical companies. The defendant reported directly to the Vice-President of Sales. At that time M&IT

¹ For clarity sake, the Government will use the same numbering conventions as the Defendant used to indicate the sections to which it is responding.

divided the United States into six business territories. The Defendant was responsible for one of the six, New York, and controlled one of the highest and busiest markets for Serostim in the country. His region was at the epicenter of the AIDS epidemic. On March 1, 1999, as well as on other occasions, the Defendant participated in discussions surrounding several “meaningful policy decisions” within the company. Further, his job was to assist in implementing and directing his sales representatives to implement company policy.

2. Contrary to the assertion of the Defendant, he did ask others to break the law.

According to the testimony of two sales representatives who reported directly to him and who testified in the Grand Jury and at trial (Konstantine Pinteris and Jeffrey Lynch), the defendant first advised them about the trip to Cannes to the doctors and invited their participation in the scheme. The sales representatives testified that they personally refused to participate in this crime (which they recognized as a kickback) and attempted to dissuade Stupak. They told the Defendant that he had to make the offers to the doctors himself. Stupak then went to the offices of the doctors and made the offer of the kickbacks to the doctors himself.

3. Contrary to the assertion of the defendant, he did benefit financially from the offers of the kickbacks and other illegal conduct engaged in by the company. The Regional Directors, including Stupak, were bonused on the amount of sales in their region. If the kickback offers to the doctors were successful in generating sales (which was what the company was asking for in return for the trip), then the sales staff, including the Defendant, would receive sales bonuses on those sales. Thus, the defendant profited from any sales that resulted from the kickback offers, as well as other illegal sales practices engaged in by the company.

4. Contrary to the Defendant’s assertions that he did not believe he was breaking the law,

the defendant has testified under oath on several occasions, including at his Plea Hearing before this Court, that he knew what a kickback was, that he knew it was illegal to offer kickbacks and that he knew it at the time that he made the offers to the doctors with whom he is charged with offering the kickbacks in this case. He repeated these statements when he testified during the trial in *United States v. Bruens, et al.*, Criminal No. 05-10102-JLT. Stupak also testified that his “gut was telling me it was wrong.” (Trial Transcript Day 6 at p. 216-217, attached hereto as Exhibit A). He also testified at trial that he knew he broke the law and that is why he plead guilty in this case. (*Id.*). Moreover, his subordinates, Konstantine Pinteris and Jeffrey Lynch both testified that they discussed this issue with the defendant before he made the offers to the doctors who were their customers.

Finally, Mr. Stupak had knowledge of the Anti-kickback statute at the time of the instant offenses. In fact, on February 26, 1999, four days prior to the meeting at the Boston Harbor Hotel, the Defendant wrote an e-mail to his superiors – Mary Stewart (VP of Sales) and John Bruens (VP of Marketing) – advising them that other companies were accusing Serono of offering kickbacks to doctors in order to sell Serostim. (*See* Trial Exhibit 183 attached hereto as Exhibit B).

This continued assertion by the Defendant is disingenuous at best. All of this evidence proves that the Defendant knew that what he was doing was wrong at the time that he committed the acts to which he has pleaded guilty. It is time for him to accept full responsibility for his actions.

C. Punishment and Deterrence:

In this section of the Defendant’s Memorandum, Stupak refers to a letter written by his

wife, Mrs. Susan Sharaby Stupak (a copy of the letter is attached to the Defendant's Memorandum as Exhibit 1). The Government recognizes the difficult position in which Mrs. Stupak finds herself as a result of her husband's criminal conduct. Mrs. Stupak's letter, however, is replete with inaccuracies, misunderstandings and fabrications. As this Court has already found, the Defendant's plea of guilty was entirely voluntary. The Court has already found that the Defendant plead guilty to the crimes because he knew that he broke the law. During the *Bruens* trial – when he had the assistance of current counsel – the Defendant testified that he made the decision to plead guilty because he broke the law. (*See* Exhibit A, Trial Transcript Day 6 at p. 217). Mrs. Stupak's ad hominem attacks on the prosecutors in this case are neither true nor helpful to the Court in these proceedings. They should not be considered by this Court.²

III. The Calculation of the Advisory Sentencing Guideline Range:

The Guideline Range as calculated in the Pre-Sentence Report is accurate and was based upon average figures and a formula that was used by and agreed to by the Company during the course of this investigation. The Defendant's attempt to re-calculate the range based upon Jeffrey Hart's testimony misconstrues that testimony and is not in accordance with the evidence in this case. By the Defendant's calculation, the cost of a prescription of Serostim was \$9,900 for a twelve week course of treatment. No payor, including any State Medicaid Agency, paid \$9,900 for a three month prescription of Serostim. This simply is not an appropriate figure to use to calculate the intended loss in this case and does not reflect the actual amount that the State

² In the event that the Court requests the Government to do so, it will respond to the any of the misstatements and misrepresentations contained in Mrs. Stupak's letter.

Medicaid Agencies, including the State of New York, paid for Serostim.

The intended loss that should be used as the basis of the guideline calculation is the amount of loss that was intended by the illegal scheme. Serostim was approved by the FDA for a twelve (12) week (3 month) course of treatment. The drug is injected daily by the patient using a syringe. The dose ranges from 4 mg. per day to 6 mg. per day, depending on the weight of the patient. The vast majority of Serostim prescriptions were for the 6 mg. dose. In fact, the sales force was trained to ask that the prescriptions be written for the full 6 mg. dose. The amounts paid for the drug and the length of the prescription varied by patient, doctor and reimbursement rates over time. Thus, there is no exact calculation to determine the exact loss.

The Average Wholesale Price ("AWP") was \$42 per mg during this time-period. The drug was initially sold at \$33 per mg. directly to "specialty pharmacies," pharmacies that specialize in supplying expensive and/or injectable drugs that are not widely prescribed. When Serono began using distributors, the price was increased to \$35 per mg. At the same time, however, the company entered into the "Data Collection Agreements" with the specialty providers, paying them \$2 per mg. purportedly for their dispensing "data." Thus, the price essentially remained the same for the various pharmacies that supplied Serostim. When claiming reimbursement for the drug, pharmacies added a dispensing fee and other added fees and/or mark-ups on the drug.

Over 85% of Serostim prescriptions were paid for by the state Medicaid Agencies. The Defendant's territory was New York. The New York State Medicaid Data obtained for 1999 indicates the reimbursement rate(s) that the agency paid to pharmacies for Serostim prescriptions. Reimbursement data for the first two quarters of 1999 indicates the amounts paid

as follows: The reimbursement rate for a 6 mg. dose of Serostim for a 30 day supply (180 mgs.) was \$6,806 per month. Thus, a twelve week course of treatment (3 months) was reimbursed by New York State Medicaid at a cost of \$20,418. The cost per milligram was \$37.81 (not the \$30 average sales price). Six (6) milligram scripts accounted for the vast majority of Serostim claims.³

The 168 mgs that formed the basis for the Government's fraud calculation was based upon a patient receiving 6 mg. per day for 28 days – even considering that 11 months are 30 or 31 days long. Using $168 \text{ mg.} \times 3 \text{ months} = 504 \text{ mgs.} \times \$42 \text{ (AWP) per mg.} = \$21,168 \text{ per script.}$ This average amount is \$750 more per script than the \$20,418 for a 30 day supply reimbursed by New York Medicaid. Using the AWP figure for a 28 day supply and multiplying \$21,168 times 30 scripts (3 doctors writing 10 scripts each) = \$635,040 – the intended loss figure. Using the actual reimbursement rate by New York State Medicaid for a 30 day supply and multiplying \$20,418 times 30 scripts (3 doctors writing 10 scripts each) = \$612,540 as an intended loss figure. Using both of these figures, there is no difference in the application of the advisory sentencing guideline range. It is the same as that used in the Pre-Sentence Report.

The defendant has taken the 110 milligrams described by Mr. Hart at trial completely out of context. The actual loss to Medicaid was not based upon Mr. Hart's calculation that night, nor was it based upon the \$30 average selling price ("ASP") – which Mr. Hart noted fluctuates. Mr.

³ The actual reimbursement rate by the New York State Medicaid Agency in 1999 for 28 days was as follows: for a 6 mg script: $\$6354 \times 3 \text{ months} = \$19,062$ at 168 mgs and \$37.82 per mg.; for a 5 mg. script: $\$5297 \times 3 \text{ months} = \$15,891$ at 140 mgs and \$37.84 per mg.; for a 4 mg. script: $\$4237 \times 3 \text{ months} = \$12,711$ at 112 mgs and \$37.83 per mg. No dosing range was as low as the 110 mgs used by Mr. Hart in his testimony, nor was any reimbursement made at the \$30 average sales price to which he testified.

Hart was talking about average amounts of prescriptions and average selling price for the purposes of calculating the revenue to Serono from the sale of Serostim. Mr. Hart was not calculating the intended loss to Medicaid for reimbursement of these Serostim prescriptions – which is the measure this Court must use for sentencing purposes.

The Cannes kickback offers to doctors were intended to fuel the "\$6 million in 6 days" sales plan. At the National Sales Meeting in March, John Bruens announced that "marketing" had invited 10 doctors to the Cannes Conference. Doing the math: 10 doctors x 30 scripts = 300 scripts. Using the AWP average of \$21,000 per script, that equals \$6,300,000 or \$6 million+.

The guideline range used in the Pre-Sentence Report is accurate and should be accepted by the Court for purposes of calculating the Sentencing Guideline range in this case.

CONCLUSION

Nevertheless, despite the differences set forth above and in the calculation of the intended loss, the sentencing recommendations of the Defendant and the Government do not differ substantially. The Defendant recommends that a sentence of six months probation is appropriate under the totality of the circumstances of this case. The Government has asked the Court to depart from the Sentencing Guidelines as a result of the defendant's substantial assistance and recommends a sentence of nine months, three months home detention followed by six months probation.

Based upon the foregoing and the Governments Motion for a downward departure pursuant to Section 5K1.1 of the Sentencing Guidelines, the government requests that the Defendant, Adam Stupak, be sentenced to nine (9) months to be served as three (3) months of

home confinement and six (6) months probation; no fine; and \$300 in special assessments.

Respectfully submitted,

MICHAEL J. SULLIVAN
United States Attorney

By: */s/ Mary Elizabeth Carmody*

MARY ELIZABETH CARMODY
Assistant U.S. Attorney

CERTIFICATE OF SERVICE

I hereby certify that these documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Mary Elizabeth Carmody

MARY ELIZABETH CARMODY
Assistant United States Attorney

Date: June 26, 2007

Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COPY

UNITED STATES OF AMERICA,

Plaintiff,

v.

JOHN BRUENS, MARY STEWART,
MELISSA VAUGHN and MARC
SIROCKMAN,

Defendants.

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)  
)  
) Criminal Action No. 05-10102-JLT  
)  
)  
) April 24, 2007, 10:03 a.m.  
) Boston, Massachusetts  
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TRANSCRIPT OF JURY TRIAL - DAY 6
BEFORE THE HONORABLE JOSEPH L. TAURO
UNITED STATES DISTRICT COURT
JOHN J. MOAKLEY U.S. COURTHOUSE
ONE COURTHOUSE WAY
BOSTON, MASSACHUSETTS 02210

Kimberly A. Smith, RDR, CRR
Marcia G. Patrisso, RPR, CRR
John J. Moakley United States Courthouse
John J. Moakley U.S. Courthouse
One Courthouse Way - Room 3507
Boston, Massachusetts 02210
(617) 737-8728

1 remember the particulars. And that was basically it."

2 "And the purpose" -- the Court asked, "The purpose
3 was to induce their purchase?" And your answer was,
4 "Was to continue to get them to write prescriptions,
5 because it's what happened, is sometimes, in all
6 businesses, you forget sometimes. And yeah, it was an
7 incentive. I felt uncomfortable."

8 And the Court said, "But was it to induce the
9 purchase of the drug?" And your answer was, "Yes."

10 Did I read that correctly, Mr. Stupak?

11 A. You read it correctly.

12 Q. Okay. And is that true?

13 A. Yes.

14 Q. And the Court accepted your plea that day, didn't
15 it?

16 A. Yes.

17 Q. Now, going back to the issue raised by counsel on
18 several occasions during your cross-examination, whether
19 or not you knew it was illegal to offer the trip to the
20 doctors to whom you offered it to, Dr. Wallach, Dr.
21 Olmscheid and Dr. Grossman. Did you know what a
22 kickback was before you made the offer to the doctors?

23 A. Yes.

24 Q. Did you know when you walked into Dr. Wallach's
25 office that you were offering him a kickback?

1 A. Yes.

2 Q. Did you know when you walked into Dr. Olmscheid's
3 office that you were offering him a kickback?

4 A. Yes.

5 Q. Did you know when you walked into Dr. Grossman's
6 office that you were offering him a kickback?

7 A. Yes.

8 Q. Did you know at that time that it was illegal to
9 offer a kickback to a doctor?

10 A. I was not sure of the legality at that time and at
11 that place; however, my gut was telling me it was wrong
12 and it shouldn't have been done.

13 Q. And you knew when you did it that you were breaking
14 the law?

15 MR. HOFFINGER: Objection. It's been asked and
16 answered.

17 THE COURT: No, I'll let her have it.

18 Go ahead.

19 THE WITNESS: I broke the law.

20 BY MS. CARMODY:

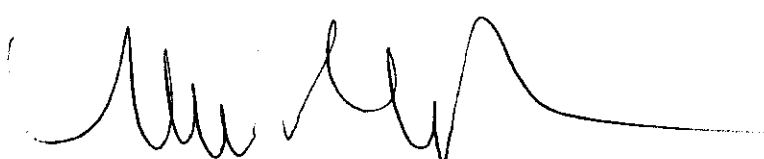
21 Q. And is that why you pleaded guilty?

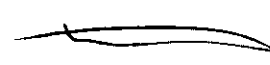
22 A. I pleaded guilty because I broke the law.

23 Q. Now, going back to the meeting of March the 1st, you
24 said you went to many meetings over the years in your --
25 in the pharmaceutical industry. Does this meeting stand

C E R T I F I C A T E

We, Marcia G. Patrisso, RPR, CRR, Official
Reporter of the United States District Court, and
Kimberly A. Smith, RDR, RPR, Court Reporter, do hereby
certify that the foregoing transcript constitutes, to
the best of our skills and abilities, a true and
accurate transcription of our stenotype notes taken in
the matter of Criminal Action No. 05-10102-JLT, United
States of America v. John Bruens, et al.



MARCIA G. PATRISSEO, RPR, CRR
Official Court Reporter

KIMBERLY A. SMITH, RDR, CRR
Court Reporter

Exhibit B



Serono

From: Adam Stupak/US_BOS01/SERONO on 02/26/99 01:29 PM
To: Scott Lundie/US_BOS01/SERONO@SERONO, John Bruens/US_BOS01/SERONO@SERONO, Mary Stewart/US_BOS01/SERONO@SERONO
cc: Thomas Browning/US_BOS01/SERONO@SERONO, Jeffrey Lynch/US_BOS01/SERONO@SERONO, Tyree Lanier/US_BOS01/SERONO@SERONO, Kostantine Pinteris/US_BOS01/SERONO@SERONO, Angelo Saverino/US_BOS01/SERONO@SERONO, Karl Safulko/US_BOS01/SERONO@SERONO, Laura Phair-Rudin/US_BOS01/SERONO@SERONO, Nancy Levine/US_BOS01/SERONO@SERONO, Selena Velez-Lebron/US_BOS01/SERONO@SERONO
bcc:
Del. date: 02/26/99 01:02:29 PM
Ref. No: ASTK/45GP4V
Subject: Competitive Update-----



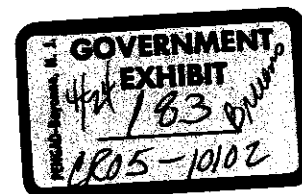
Competitive Update-----

Unimed and BTG are going after Serostim on price. They are also making claims that we give kick backs. It sound like they are using the Moody paper.

BTG has a study at Mt. Sinai using 20/40 mg dosing in women; 40/80 mg in men. They're using the new tablets which combines the tablets into one, reduceing the pill burden. Dr. Gurtman is the investigator.

UniMed Reg. Dir. said that they are hiring 4 reps. 1 in NYC, 1 in Bronx, 1 in Brooklyn/ SI, and 1 Queens/ LI.

Adam



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